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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,058	09/11/2003	Craig Heacock	CP245	7280

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
11/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/660,058	HEACOCK ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,5,7-9,11-24,26,27,29,31-33,35-42,45 and 46* is/are pending in the application.

4a) Of the above claim(s) *11-17 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,5,7-9,18,20-24,26,27,29,31-33,35-42, 45 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on August 8, 2007 have been received and entered into the application.

Action Summary

The objection of claims 43 and 44 are objected to because of the informalities is hereby expressly **withdrawn** in view of Applicants' amendment of cancellation of the claims.

The rejection of claims 2, 3, 5, 7-9, 18, 20-24, 26, 27, 29, 31-33, 38-42, 45 and 46 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 30 and 31 of U.S. Patent No. 6,919,378 B2 is being **maintained** for the reasons stated in the previous Office Action.

The rejection of claims 2, 3, 5, 7-9, 18, 20-24, 26, 27, 29, 31-33, 38-42, 45 and 46 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 26 and 35-39 of U.S. Patent No. 6,489,363 B2 is being **maintained** for the reasons stated in the previous Office Action.

The provisional rejection of claims 2, 3, 5, 7-9, 18, 20-24, 26, 27, 29, 31-33, 38-42, 45 and 46 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 62-75 of copending Application No. 10/155,913 is being **maintained** for the reasons stated in the previous Office Action.

The provisional rejection of claims 2, 3, 5, 7-9, 18, 20-24, 26, 27, 29, 31-33, 38-42, 45 and 46 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 93, 94, 97 and 98 of copending Application No. 10/243,557 is being **maintained** for the reasons stated in the previous Office Action.

The provisional rejection of claims 2, 3, 5, 7-9, 18, 20-24, 26, 27, 29, 31-33, 38-42, 45 and 46 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of copending Application No. 11/550,588 is being **maintained** for the reasons stated in the previous Office Action.

The rejection of claim 36 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is hereby expressly **withdrawn** in view of Applicants' amendment.

The rejection of claims 1, 4, 6, 18, 21, 25, 28, 30 and 35 under 35 U.S.C. 102(b) as being anticipated by Laurent (U.S.Patent No. 5,401,776) is hereby expressly **withdrawn** in view of Applicants' amendment.

The rejection of claims 2, 3, 5, 7-10, 20, 22-24, 26, 27, 29, 31-34 and 38-44 under 35 U.S.C. 103(a) as being unpatentable over Laurent (U.S.Patent No. 5,401,776) is being **maintained** for the reasons stated in the previous Office Action. However, the rejection is modified in this office Action to exclude the cancelled claims.

The rejection of claims 35, 36 and 37 under 35 U.S.C. 103(a) as being unpatentable over Laurent (U.S.Patent No. 5,401,776) further in view of Lawyer et al.

(US 2003/0171439A1) is being **maintained** for the reasons stated in the previous Office Action.

Response to Arguments

Applicants' arguments filed on August 8, 2007 have been fully considered but they are not persuasive. Applicants argue that there is no suggestion or incentive for one skilled in the art to modify the weight-based dosing regime described in Laurent so as to employ the flat dosing regime set forth in the present application because favorable effective results were obtained in both of the examples using flat dose and mg/kg dose of modafinil. This is not found persuasive because it is noted that Laurent's flat dose of 400mg exemplified in tables I and II are employed for the subject population of adults and elderly patients with vesicosphincteral disorder associated with a cervicosphincteral insufficiency. (column 1, lines 46-50). However, the weight-based dosing was employed for the subjects average of 10 years of age, e.g. children. Therefore, there is a suggestion from Laurent that weight-based dosing is preferred in children. One of ordinary skill in the art would recognize that flat dosages of 400mg tablet are appropriate for the adults and that the weight-based dosing as exemplified for the children would serve as useful guideposts for the physician in determining optimum dosage to be utilized for children populations to be treated. Therefore, there is a motivation to formulate a composition comprising modafinil with the amounts within the preferred range from 5 to 100mg/kg, particularly, 10mg/kg, specifically targeted for children. Applicants argue that Lawyer fail to cure the deficiencies of Laurent. This is

not found persuasive because Lawyer et al. teaches that the inactive ingredients set forth in claims 36 and 37 are well known ingredients but have undesirable effects of causing allergic reaction in some patients. Therefore, it would have been obvious to one of ordinary skill in the art to modify the content of well-known inactive ingredients of modafinil tablets for the particularly sensitive patients to be treated because those inactive ingredients have undesirable effects in some of patients as taught by Lawyer et al. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2, 3, 5, 7-9, 18, 20-24, 26, 27, 29, 31-33, 38-42, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laurent (U.S.Patent No. 5,401,776) of record.

Laurent teaches a medicament containing modafinil for the treatment of urinary and fecal incontinence and urethrovesical and anal sphincteral disorders. (abstract). Laurent teaches the modafinil containing medical product may be provided especially in a form suitable for oral administration. Laurent teaches the modafinil-containing medicinal product in a single dose of 400mg. (column 2, particularly, Table I and II).

Laurent also teaches the administered doses may be from 1mg/kg to 100mg/kg and **preferably from 5 to 100mg/kg**. (column 1, lines 35-40).

Laurent does not teach the specified amounts in "mg" of modafinil set forth in claims, percentages of modafinil in a tablet and the blood plasma level of modafinil set forth in claim 18.

However, Laurent teaches preferred amounts to be administered expressed in mg/kg, **5 to 100mg/kg** in a table formulation. Laurent exemplify mg/kg based dosing for children with mean age of about 10.

It would have been obvious to one of ordinary skill in the art to formulate medicament containing modafinil within the preferred amounts based on weight for the children dosing taught by Laurent because Laurent exemplifies determination of children dosing of modafinil by mg/kg (e.g. 10mg.kg) for the treatment of urinary and fecal incontinence in children. One of ordinary skill in the art would have been motivated to employ the amounts with in the preferred range from 5 to 100mg/kg, particularly 10mg/kg in order to customize the specific dosages required for the specific populations to be treated. The specific amounts recited in the instant claims are obvious because they fall within the preferred dosages taught by Laurent for patients population of adults and children. As anyone of ordinary skill in the art will appreciate, preferred dosages are merely exemplary and serve as useful guideposts for the physician. There are, however, many reasons for varying dosages, including by orders of magnitude; for instance, an extremely heavy patient or one having an unusually severe disease condition would require a correspondingly higher dosage while children

or elderly having less server disease condition would require more customized weight based dosages. Furthermore, it is routine during animal and clinical studies to dramatically vary dosage to obtain data on parameters such as toxicity and efficacy. For these and other self-evident reasons, it would have been obvious to have used specific customized dosage based on their weight particularly for children suffering from incontinence as taught by Laurent. With regard to the blood plasma level of modafinil set forth in claim 18 is obvious because Laurent teaches the mg/kg dosing to be administered preferably from 5 to 100mg which encompasses and touches the amounts set forth in claim 18. Therefore, the upon the administration of modafinil to 30kg child based on Lauren's exemplified 10mg/kg would obviously achieve the same blood plasma level as recited in claim 18.

Furthermore, no unobviousness is seen in the percentages of active agent in a single tablet claimed because it is routine manufacturing process to optimize the percentages of the ingredients in a single formulation.

Claims 35, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laurent (U.S.Patent No. 5,401,776) of record as applied to claims 2, 3, 5, 7-9, 18, 20-24, 26, 27, 29, 31-33, 38-42, 45 and 46 above and further in view of Lawyer et al. (US 2003/0171439A1).

Laurent as applied as before.

Laurent does not teach the specific diluents, disintegrants, binder and a lubricant set forth in claims 36 and 37.

Lawyer et al. teach that Applicants' specific diluents, disintegrants, binder and a lubricant set forth in claims 36 and 37 are well known inactive ingredients in modafinil-containing tablets. Lawyer et al. teach, however, those inactive ingredients including magnesium silicate and talc may be considered undesirable because some people may dislike or be allergic to one or more of these inactive ingredients in the modafinil tablets.

It would have been obvious to one of ordinary skill in the art to modify the content of well-known inactive ingredients of modafinil tablets because those inactive ingredients are well-known to be formulated with modafinil but one or more of the inactive may be disliked or develop allergic reaction to some people. One would have been motivated to customize the inactive content by the patient's allergy profile in order to avoid allergic reaction taught by Laurent. There is a reasonable expectation of successfully elimination one or more of inactive ingredient well known to be formulated with modafinil in order to accommodate some people who dislike or are actually allergic to some of those inactive ingredients.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2, 3, 5, 7-9, 18, 20-24, 26, 27, 29, 31-33, 38-42, 45 and 46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 30 and 31 of U.S. Patent No. 6,919,378 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent encompasses same subject matter of composition comprising modafinil. The difference is the specified dose of modafinil. However, it would have been obvious to one of ordinary skill in the art to formulate modafinil composition taught by the Patent with optimum dosage amounts adjust to any given patient to be treated in order to customize the specific amounts need according to his severity and medical profile of the condition.

Claims 2, 3, 5, 7-9, 18, 20-24, 26, 27, 29, 31-33, 38-42, 45 and 46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 26 and 35-39 of U.S. Patent No. 6,489,363 B2 of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent encompasses same subject matter of composition comprising modafinil. The difference is the specified dose of modafinil. However, it would have been obvious to one of ordinary skill in the art to formulate modafinil composition taught by the Patent with optimum dosage amounts adjust to any given patient to be treated in order to customize the specific amounts need according to his severity of the condition.

Claims 2, 3, 5, 7-9, 18, 20-24, 26, 27, 29, 31-33, 38-42, 45 and 46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 62-75 of copending Application No. 10/155,913. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in copending application and the instant claims are drawn to same subject matter of composition comprising modafinil. The difference is the specified dosage amount of modafinil and the excipients. However, the amounts of active agents or the excipients to be use are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations and modes of administration.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 2, 3, 5, 7-9, 18, 20-24, 26, 27, 29, 31-33, 38-42, 45 and 46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 93, 94, 97 and 98 of copending Application No. 10/243,557. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in copending application is drawn to same or overlapping percentages of modafinil as recited in instant claims. The difference is the specified dosage amounts in mg of modafinil and the excipients. However, the amounts of active agents or the excipients to be use are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations and modes of administration.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 2, 3, 5, 7-9, 18, 20-24, 26, 27, 29, 31-33, 38-42, 45 and 46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of copending Application No. 11/550,588. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in copending application and the instant claims are

drawn to encompassing or overlapping dosage amount of modafinil as recited in instant claims. The difference is functional language of the composition release two or more amounts of a modafinil compound. However, the amounts of active agents released over period of time is not constant upon the ingestion because the amount depletes over time due to metabolism. Further, the formulation of sustained release or the extended release is obvious because they are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent readily available conventional formulations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

None of the claims are allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Kim
Primary Examiner
Art Unit 1617

Jmk
October 27, 2007